

REMARKS

Claims 16-25 and 52-53 are pending. Claims 1-15 and 26-51 are canceled. Claims 52 and 53 are new and find support at least in original claim 17. Claim 16 is currently amended and finds support at least at paragraphs [0019] and [0054] of the specification. Claim 24 is currently amended and finds support at least at paragraph [0087] of the specification. No new matter is entered.

Outstanding Issues:

- Claim 16-25 were discussed in an Examiner's Interview on September 3, 2008. Novelty over the prior art was provisionally agreed to between the Examiner and the Applicants given an amendments of the claims to treatment of diabetic ulcers. The Applicants thank the Examiner for the Interview.
- Claims 16-51 are rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement.
- Claims 16-18, 21-23 and 26-51 are rejected under 35 U.S.C. § 102(a) as anticipated by Boyko *et al.* (WO 02/03910; "Boyko").
- Claim 15 is rejected under 35 U.S.C. § 103(a) as obvious over Ando *et al.* (US Pat. 5,576,299; "Ando") in view of Ogunbiui *et al.*, (US Pat. 4,783,488; "Ogunbiui").
- Claims 16, 17, 21-23, 26, 28 and 30-47 are rejected under 35 U.S.C. § 103(a) as obvious over Kruzel *et al.* (US Patent 6,066,469; "Kruzel")
- Claims 15-51 are provisionally rejected under the judicial doctrine of obviousness-type double patenting over US Patent 7,323,443 (patented from US Application No. 10/733,621)
- Claims 16-22, 26-30 and 50-51 are provisionally rejected under the judicial doctrine of obviousness-type double patenting over US Patent Application No. 10/728,521.

I. Rejection under 35 U.S.C. § 112 ¶ 1 – Written description

Claims 16-51 are rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement. Specifically, the claims are rejected as containing new matter. Applicant respectfully traverses.

While the Applicant does not necessarily agree with the new matter rejection independent claim 16, and thereby dependent claims 17-25, are herein amended to remove reference to duodenal ulcers. Applicant respectfully requests withdrawal of the rejection.

II. Rejection under 35 U.S.C. § 102(a) as anticipated by Boyko

Claims 16-18, 21-23 and 26-51 are rejected under 35 U.S.C. § 102(a) as anticipated by Boyko *et al.* (WO 02/03910; “Boyko”). Applicant respectfully traverses.

To anticipate a claim, the reference must teach every element of the claim (MPEP § 2131). Boyko does not teach the treatment of diabetic ulcers with lactoferrin or the treatment of subjects having diabetic ulcers, as given in the currently amended claims. Thus, Boyko does not anticipate the current claims.

Applicant kindly requests withdrawal of the rejection.

III. Rejection under 35 U.S.C. § 103(a) as obvious over Ando in view of Ogunbiui

Claim 15 is rejected under 35 U.S.C. § 103(a) as obvious over Ando in view of Ogunbiui. Applicant respectfully traverses.

While the applicant does not necessarily agree with the Examiner on the anticipation rejection, claim 15 is herein canceled without prejudice and without acquiescence. As the rejection no longer applies to the current claim set, Applicant respectfully requests withdrawal of the rejection.

IV. Rejection under 35 U.S.C. § 103(a) as obvious over Kruzel

Claims 16, 17, 21-23, 26, 28 and 30-47 are rejected under 35 U.S.C. § 103(a) as obvious over Kruzel. Applicant respectfully traverses.

For a *prima facie* case of obviousness to be made, all claim limitations must be accounted for (MPEP 2143.03). Kruzel at least does not teach or suggest the treatment of diabetic ulcers, or the administration of lactoferrin to a subject having a diabetic ulcer as required by the currently amended claims. Thus, Kruzel does not support a *prima facie* case of obviousness for the claims as amended herein.

Applicant respectfully requests withdrawal of the rejection.

V. Rejected under the judicial doctrine of obviousness-type double patenting over U.S. Patent 7,323,443 (patented from U.S. Application No. 10/733,621)

Claims 15-51 are provisionally rejected under the judicial doctrine of obviousness-type double patenting over U.S. Patent 7,323,443 (patented from US Application No. 10/733,621). Applicants respectfully traverse in view of the amendments herein.

U.S. Patent 7,323,443, has a single independent claim 1 directed to method of treating pain associated with recovery from surgery by administering to a subject an effective amount of a lactoferrin composition. In comparison, currently amended claim 16 is directed to treating diabetic ulcers. The Examiner's position on double patenting for the prior pending claims was:

Both the claims of instant application and the claims of the patent are directed to a method of treating wound or a patient having a pain from surgery by administering a lactoferrin composition (i.e., the same method steps), where a patient having a pain from surgery would have a wound. Thus, claims 15-51 in present application and claims 1-16 in the patent are obvious variations of a method of treating wound or pain from surgery (a wound) by administering a lactoferrin composition.

While Applicant does not necessarily agree with the Examiner's original position, Applicant submits that the above rationale is clearly mooted by the amendments made herein. In view of the above, Applicants respectfully request withdrawal of the rejection.

VI. Rejection under the judicial doctrine of obviousness-type double patenting over US Patent Application No. 10/728,521

Claims 16-22, 26-30 and 50-51 are provisionally rejected under the judicial doctrine of obviousness-type double patenting over US Patent Application No. 10/728,521. Applicants traverse.

Applicant respectfully submits that the above provisional rejection is the only rejection still pending in view of the foregoing response. US Patent Application 10/728,521 has a filing date of 12-05-2003. The instant application has an earlier filing date of 09-16-2003. Further:

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

MPEP § 804. Thus, since the current application has the earlier filing date, the provisional nonstatutory obviousness-type double patenting rejection should be withdrawn, and the application should be allowed to issue as a patent.

Applicants respectfully request withdrawal of the provisional double patenting rejection.

CONCLUSION

In view of the above, applicant believes the pending application is in condition for allowance.

Applicant believes no fee additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02652US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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